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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,753	02/06/2002	Abraham Amir	02/23230	4762

7590 05/04/2004

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,753	AMIR ET AL.	
	Examiner	Art Unit	
	Susan Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed March 15, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1 and 3-14 are pending.
3. In Paper No. 5, dated November 25, 2002, applicant elected of Group I, claims 1-8, without traverse.
4. Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.
5. Claims 1 and 3-8 are examined on the merits.

Claim Rejections - 35 USC § 103

6. Claims 1, 3, 4, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,469,676 in view of Brittberg et al. (NEJM (1994), vol. 331, pp. 889-895).

US '676 teaches a method of treating wrinkles by injecting cartilage cells into the wrinkle (see claims). However, US '676 does not teach using isolated cartilage producing cells, i.e. chondrocytes, to treat wrinkles. Brittberg teaches that isolated chondrocytes can be administered via injection for use in reconstructive surgery (see page 4). Brittberg teaches that the purpose of injecting the chondrocytes is to produce cartilage at the injection site. The function of US '676 is also to introduce cartilage into the treatment site. Thus, Brittberg shows that it was known in the art that isolated chondrocytes can be used for the same purpose as the cartilage of US '676. Based on this teaching by Brittberg, a person of ordinary skill in the art would reasonably expect

Art Unit: 1654

that isolated chondrocytes could be successfully used in place of the cartilage cells in the method taught by US '676. Therefore, based on this reasonable expectation of success, an artisan of ordinary skill would have been motivated to treat wrinkles by subcutaneously injecting chondrocytes into the site of the wrinkle.

7. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,469,676 and Brittberg as applied to claims 1, 3, 4, 7, and 8 above, and further in view of Atala et al. (J. Urol. (1993), vol. 150, pp. 745-747).

As discussed above, the combination of US '676 and Brittberg teach using chondrocytes to treat facial irregularities. Brittberg specifically teaches using chondrocytes isolated from the subject. Neither reference specifically teaches using chondrocytes harvested from a syngeneic source, or an allogeneic source. However, Atala teaches that chondrocytes isolated from a different species can be safely injected into a subject in order to produce cartilage. Based on this teaching of using chondrocytes isolated from a different species than the subject, a person of ordinary skill in the art would have a reasonable expectation that using chondrocytes harvested from a syngeneic source or an allogeneic source in the method taught by the combination of US '676 and Brittberg would be successful. If cells from a xenogeneic source do not produce adverse effects, it is reasonable to expect that cells from the syngeneic source or an allogeneic source would also not produce adverse effects while still imparting the same benefits to the skin. Therefore, a person of ordinary skill in the art would be motivated to use chondrocyte cells from a syngeneic source or an allogeneic source in the skin treatment method taught by the combination of Brittberg and US '676.

Art Unit: 1654

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan D. Coe, Examiner
April 27, 2004


LEON B. KANKEFORD, JR.
PRIMARY EXAMINER